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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 359,300	07 21 1999	MONTO H. KUMAGAI	08010137US07	2643

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09 10 2002

37

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/359,300

Applicant(s)

KUMAGAI ET AL

Examiner

Gerald Leffers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 32
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The request filed on 6/21/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/359,300 is acceptable and a CPA has been established. An action on the CPA follows. Receipt is acknowledged of an amendment, filed 6/21/02 as Paper No. 34, in which claim 45 was amended to read on the same subject matter as claimed in original claims 4 and 6.

Claims 45 and 60-70 are pending in this application and under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45 and 60-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of determining a trait in a plant where unknown nucleic acids are transiently expressed from plant viral vectors and where infected and uninfected plant cells of the same type (e.g. *Nicotiana benthamina* or *Nicotiana cleavlandii*, etc.) are compared, does not reasonably provide enablement for embodiments using non-plant viral vectors or where the step of correlating observed changes involves plant cells of different types. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of

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working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Each of the claims comprise the limitations that a library of DNA or RNA sequences that are unidentified are transiently expressed in plant host cells from recombinant viral nucleic acids. The results of expression of an unidentified nucleic acid sequence in a plant host cell is then "correlated" to an uninfected host cell, and a trait identified in either the infected or uninfected host cell. The claims are broad in scope in that they encompass embodiments wherein bacteriophage or animal viral vectors are used to express the unknown sequences in host cells. Also, the claims encompass embodiments where infected cells of one type are compared to uninfected cells of another type, and a trait identified (e.g. *N. benthamina* -vs.- *A. thaliana*). The only recombinant viral nucleic acids disclosed by the specification as working in plants are ones obtained from plant viruses. The specification does not clearly define or teach what is meant by "correlating" the changes observed in step (d) of the claimed method to an uninfected plant host cell, much less teach how one would do so for plant host cells of differing origin. The prior art does not appear to compensate for the deficiencies of the instant specification in that it does not appear to address these issues either. Therefore, it would take undue, unpredictable experimentation to practice the claimed methods with 1) viral vectors that were not of plant virus origin, and 2) correlating results of step (d) in a plant host cell of one type with an uninfected cell of a differing type. It would be remedial to amend the claims to clearly indicate that 1) the recombinant viral nucleic acids are obtained from a plant virus, and 2) that the correlating step involves plant host cells of the same type.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45 and 60-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 is vague and indefinite in that the metes and bounds of the phrase "...correlating said one or more phenotypic or biochemical changes to a host plant that is uninfected..." are unclear. The specification does not clearly illustrate what is involved in "correlating" a phenotypic or biochemical change observed in a test plant to a control plant that has not been infected with the recombinant viral nucleic acid of the invention. Are there multiple steps involved in "correlating" the observed changes to a control plant and what is the end-result of the correlation step? Does the phrase specify that one simply compare the test plant to the control plant to determine if the same biochemical or physical changes are observed in the control plant? It would be remedial to amend the claim language to clearly indicate the number and nature of steps involved in "correlating" an observed biochemical or phenotypic change in a test plant to the control, uninfected plant. It will also be necessary to clearly indicate the end result of such "correlation".

Claim 45 is vague and indefinite in that the relationship between the biochemical or phenotypic change(s) observed in the test plant of step (d) and the identified trait of step (f). First, can the trait observed in (f) be the same as one of the biochemical or phenotypic changes in step (d)? There appears to be significant overlap between what constitutes an observed

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phenotypic or biochemical change and what constitutes a "trait" in terms of the claimed invention (e.g. pages 24-25 of the instant specification). Secondly, is there necessarily a causal relationship between the trait observed in step (f) and the changes observed in step (d)? It would be remedial to amend the claims to clearly indicate the differences, if any, between an observed "change" and an observed "trait", as well as indicating the functional relationship between what is observed in step (d) and what is observed in step (f).

Claim 45 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "said plant hosts" in step (d) of the claim. The plant hosts could be uninfected or infected as the claim is written. Judging from the specification and the claim structure, it appears that step (d) is more properly directed to only the infected plant host cells. Also, there is no explicit language in the claim that indicates that the infected and uninfected plant hosts are necessarily the same organism (e.g. *Nicotiana benthamina*, etc.). Upon reading the specification, it appears that it is intended in practicing the claimed method for one to correlate the infected host plant results to an uninfected plant of the same type. Modification of the claim language to clearly indicate that the uninfected and infected host cells are of the same type would clarify this issue.

Claims 60-63 are vague and indefinite in that there is no clear and positive prior antecedent basis for the term "said plant host". It would be remedial to amend the claims to clearly indicate that the term refers to either the infected or uninfected plant host cells, or both.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

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ggl

September 9, 2002

DAVID GUEZ
PRIMARY EXAMINER

David Guez